

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

April 19, 2012

DP BARCODE: 399984

MRID : NA

SUBJECT: HeiQ AGS-20 (and HeiQ AGS-20 U)
(Name of Product)

REG. NO.: 85249-1 and 85249-2

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☒ OR End-use Product ☐

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
072599	7440-22-4	Silver *

*includes particles in the size range between 1 to 100 nm

TEST LAB: NA

APPLICANT: HEIQ Materials AG
Zürcherstrasse 42
5330 Bad Zurzach Switzerland

GUIDELINE: NA

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: April 19, 2012

COMMENT:

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. No.: 85249-1 and 85249-2
Product Name: HeiQ AGS-20 and HeiQ AGS-20 U
DP Barcode: 399984

CODE: (360) Action Initiated by the Agency

DATE DUE: June 20, 2012

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Earl Goad 4/19/2012

THRU: Jed Costanza, Ph.D.
Staff, Regulatory Management Branch I
Antimicrobials Division (7510P)

Jed Costanza

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

*Karen Hicks
for KPM 4/24/12*

TO: Marshall Swindell PM#33/Demson Fuller
Regulatory Management Branch I
Antimicrobials Division (7510P)

Marshall Swindell 4/24/12

Applicant: HEIQ Materials AG
Zürcherstrasse 42
5330 Bad Zurzach Switzerland

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Silver *	19.3
<u>Other Ingredient(s):</u>	<u>80.7</u>
Total:	100.00

*includes particles in the size range between 1 to 100 nm

BACKGROUND:

The Agency is requesting that the registrant HeiQ Materials AG provide certain Product Chemistry registration items, which were identified in the June 30, 2009 Product Chemistry Review for their conditionally registered product HeiQ AGS-20 (EPA Reg. no. 85249-1). These recommendations also apply to HeiQ AGS-20 U (EPA Reg. no. 85249-2)

Documents included for the purpose of this review:

1. Copy of Product Chemistry Review for HeiQ AGS-20, DP# 364587, EPA Reg. no. 85249-1, dated June 30, 2009.
2. An accepted product label, stamped December 1, 2011.
3. Basic Confidential Statement of Formula (CSF) for HeiQ AGS-20 EPA Reg no. 85249-1, dated September 8, 2008 (Pre-Post Reaction pp 1 – 3) and the Basic CSF for HeiQ AGS-20 U EPA Reg. no. 85249-2, dated August 20, 2010 (Pre-Reaction pp 1 & 2, post page 1)

FINDINGS and RECOMMENDATIONS: The following items apply to both 85249-1 and 85249-2.

1. Basic CSF pages one and two represent a pre-reaction CSF which includes the ingredients, suppliers, and a description of the production process. Page three is a post reaction CSF which should represent the composition of the final product. CTT finds this Post Reaction CSF to be incomplete as was previously indicated. The following CSF revisions are being requested starting the first row under POST-REACTION CSF for both products.

<u>Row 1 column</u>	10 remove "Purity: 19.3%" 13a & b, 14 a & b, leave blank 15 enter [REDACTED]
<u>Row 2 column</u>	10 enter "Silver* (CAS# 7440-22-4)" **Includes particles in the size range 1 to 100 nm" 13b enter "19.3" 14a enter [REDACTED] 14b enter [REDACTED] 15 enter "Active Ingredient"
<u>Row 3 column</u>	10 enter [REDACTED] 13a enter [REDACTED] 14a enter [REDACTED] 14b enter [REDACTED] 15 enter [REDACTED]
<u>Top of CSF</u>	Box 4 enter the registration number 85249-1 or 85249-2 (as appropriate).
<u>Bottom of CSF</u>	Box 17 Total Weight leave blank Box 21 Date enter date of signature of revised CSF.

Each page must include: Product name, EPA Reg no., signature, signature date, and Page # of Total #

2. As requested in Product Chemistry OSCPP 830.1750 § (g) Certified Limits Guideline, please provide a separate signed certification statement for 85249-1 and 85249-2. The following statement, signed and dated by the authorized representative of the company, is acceptable. The text for this statement is found in guideline or in the 40CFR § 158.350 (e) or 40CFR § 161.175 (e) and is provided here.

I hereby certify that for purposes of FIFRA section 12(a)(1)(C), the description of the composition of [product name], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: No ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently-approved Statement of Formula (or as calculated by the Agency); and if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

CONCLUSIONS:

The current Basic CSFs for EPA Reg. no. 85249-1 HeiQ AGS-20 and 85249-2 HeiQ AGS-20 U must be revised to conform to recommendations as listed in FINDINGS 1. Certification statements regarding "Certified Limits" must also be provided because they were not submitted with the initial application package.